REMARKS

Status of the Claims

Claims 1-3 and 5-13 are pending in the present application. Claims 1-3 and 5-13 are rejected. Claim 4 was previously canceled. Claims 1 and 2 were amended in the response filed September 30, 2008. An Advisory Action was issued on October 23, 2008, which stated that the amendment would not be entered. In lieu of the amendment filed on September 30, 2008, Applicants are requesting entry of the present amendment submitted herein. Claims 1 and 2 are amended herein without prejudice or disclaimer. The amendments are supported throughout the specification as originally filed, including, *e.g.*, on pages 6-7 bridging paragraph (claim 1) and on page 6, lines 25-28 (claim 2). Entry and reconsideration is respectfully requested.

Issues Under 35 U.S.C. § 112, Second Paragraph

Claims 1 and 13 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. (*See*, Office Action of July 2, 2008, at page 2, hereinafter, "Office Action" and Advisory Action of October 23, 2008, hereinafter "Advisory Action"). Specifically, the Examiner asserts that the term "benzophenoneimine" is unclear, *see* Office Action, page 2. The Examiner further states that the term "diphenylmethylamino", as submitted in the response filed September 30, 2008, is unacceptable because the term allegedly lacks support in the instant application, *see* Advisory Action, October 23, 2008, page 2. Applicants respectfully traverse the rejection.

Although Applicants do not agree with the Examiner's allegations, to expedite prosecution, claim 1 has been amended to replace the term "benzophenoneimine" for R' and R"

in claim 1 with "diphenylmethylimino." In addition, claim 2 has been amended to replace the term "aryl" for R6 and R7 with the term "phenyl" for consistency with the claim 1 amendment.

Since no specific reasoning is provided for the rejection of claim 13, claim 13 is believed to be definite for, *inter alia*, depending from a definite base claim, amended claim 1.

Reconsideration and withdrawal of the indefiniteness rejection of claims 1 and 13 are respectfully requested.

Issues Under 35 U.S.C. § 112, First Paragraph

Claims 1-3 and 5-13 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. (*See*, Office Action, at pages 3-33 and Advisory Action, pages 2-4). Specifically, the Examiner states that the present application teaches that the claimed compounds may be used as anti-cancer agents, anti-viral agents and the like, *see* Office Action, page 3. The Examiner states, however, that while the compounds need only a single utility to be enabled, the single utility is not met by the present application, *see* Office Action, page 3 and Advisory Action, page 3. The Examiner asserts that the utility described by Applicants, which Applicants state is further supported by, *e.g.*, PCT Publication No. WO 00/75158, is insufficient to support a use of the claimed purine compounds because the purine compounds described in PCT Publication No. WO 00/75158 may include substituents, which differ from those of the instantly claimed compounds, *see* Advisory Action, page 3. The Examiner further alleges that the large numbers of cancers and viruses would preclude the public from using the claimed compounds without undue experimentation, *see* Office Action, page 3. In support of these assertions, the Examiner cites *In re Gardner et al.* 57 CCPA 1207, 427 F.2d

786, 166 USPQ 138 (1970), which the Examiner states holds that composition of matter claims were found to lack enablement because they lacked an enabling utility *see* Office Action, page 11, *see also* Advisory Action, page 3. Applicants respectfully traverse the rejection.

In order to establish a *prima facie* case of non-enablement, the Examiner must explain why the specification is not enabled based upon sound scientific reasoning or acceptable evidence, which is inconsistent with the statements in the specification asserting enablement. *In re Marzocchi*, 169 USPQ 367 (CCPA 1971). If a statement of utility in the specification contains within it a connotation of how to use, 35 U.S.C. 112 is satisfied. *In re Johnson*, 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); *In re Hitchings*, 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965). *See also In re Brana,* 51 F.2d 1560, 1566, 34 USPQ2d 1437, 1441 (Fed. Cir. 1993). "What is necessary to satisfy the how-to-use requirement of 112 is the disclosure of some activity coupled with knowledge as to the use of this activity", *see In re Bundy*, 642 F.2d 430, 434, 209 USPQ 48, 51 (CCPA 1981).

As noted previously, the present application teaches that purine compounds are well-known in the art to have anti-cancer activity or anti-viral activity, *see, e.g.* page 1, lines 7-10, and pages 44-45, bridging paragraph, in the application as originally filed. The present application further cites, for example, PCT Publication No. WO 00/75158, as evidence of the many reports of the well-known utility of purine compounds as anti-cancer agents, *see* page 1, line 10 in the originally filed application. Applicants submit that these statements of utility in the instant application and the support cited contain a connotation of how to use the claimed compounds. For example, PCT Publication No. WO 00/75158, teaches that purines are known in the art to be useful as chemotherapeutic agents, in particular for Hodgkin's lymphoma, ovarian cancer, small-

cell lung carcinoma, skin cancers and prostate cancer, *see*, *e.g.*, page 1 lines 25-30 in PCT Publication No. 00/75158. In addition, chemotherapy of neoplasias is the subject of numerous monographs and specialized scientific and clinical journals, *see*, *e.g.*, pages 1-2, bridging paragraph, of PCT Publication No. WO 00/75158.

Notwithstanding the foregoing, the Examiner believes that the amount of experimentation required to use the claimed compounds is undue. The Examiner cites *In re Gardner et al.* in support of this assertion. In *In re Gardner*, the claims were directed to compositions having an antidepressant activity. In *In re Bundy,* 642 R2d 430, 209 USPQ 48, 51, the court said that such claims are distinguishable from composition of matter claims that do not specify a use. In particular, the court in *In re Bundy* stated:

> We do not consider that one of ordinary skill in the art would not know how to use these novel analogs ...This is not the same situation as in *In re Gardner et al.*, 57 CCPA 1207, 427 F.2d 786, 166 USPQ 138 (1970). Here only the compounds themselves are being claimed, not their therapeutic use....

As noted above, the court further stated that "[w]hat is necessary to satisfy the how-to-use requirement of 112 is the disclosure of some activity coupled with knowledge as to the use of this activity." *Id.*

In the instant application, the claims are directed to compositions of matter and production methods thereof. Accordingly, the standard for determining compliance of the instant claims under the how-to-use requirement of 35 U.S.C. § 112, first paragraph, is the disclosure of some activity coupled with knowledge as to the use of that activity. Applicants submit that the present application meets this burden. The instant specification teaches that the claimed compounds are useful for their anti-cancer and anti-viral activity and a skilled artisan would

know how to use compounds having this activity, *see, e.g.* PCT Publication No. WO 00/75158. Applicants further submit that the Examiner has not provided sufficient reasons that would cause a skilled artisan to doubt Applicants' assertion.

Applicants wish to emphasize that because the original claims relate to a compound and a production method thereof, the enablement of the claims should be judged based upon the enforceability of the claimed invention itself. The presently claimed invention relates to a compound *per se*, rather than any treatment method of a disease. Accordingly, as long as the specification teaches those of ordinary skill in the art a method of producing the compound (how to make) and how the compound can be used, the enablement requirement is satisfied.

It is respectfully submitted that inasmuch as the compound and the production method of the presently claimed invention are sufficiently described in the specification, the holding of the Examiner is clearly incorrect.

Moreover, an explicit production method of the compound of the presently claimed invention may be found in the Examples of WO 00/75158, which is itself described at page 1 of the present specification. (*See also*, Petr Capek et al., "Synthesis of Enantiomerically Pure (Purin-6-yl)phenylalanines and Their Nucleosides, a Novel Type of Purine-Amino Acid Conjugates", J. Org. Chem. 2005, Vol. 70, pp. 8001-8008, filed in an Information Disclosure Statement on even date herewith). Therefore, there is clearly no undue experimentation required by one of skill in the art to obtain the presently claimed compounds.

More specifically, claims 9-12 are directed to methods of producing the presently claimed compounds, not treatment methods. Since the methods of production are described in the present specification in a manner in which one of skill in the art can comprehend and duplicate in the

laboratory, it is clear that there are not grounds upon which the Examiner can reject the presently claimed invention under 35 U.S.C. § 112, first paragraph.

Based upon the foregoing, Applicants submit that a person of skill in the art would understand from the instant specification and the prior art how to use the instantly claimed compounds. Applicants further submit that a skilled artisan would have understood from the instant specification and the knowledge in the art how to make the claimed compounds. Accordingly, claims 1-3 and 5-13 satisfy the enablement requirement and Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

CONCLUSION

If the Examiner has any questions or comments, please contact Linda T. Parker, Ph.D., Registration No 46,046, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: DEC 0 2 2008

Respectfully submitted,

By _____

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